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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete If Known | | | |
| | | Application Number | 10/719,007 | | |
| | | Filing Date | November 20, 2003 | | |
| | | First Named Inventor | JOHNSON, RANDOLPH MELLUS | | |
| | | Art Unit | 1615 | | |
| Sheet | 1 | of | 3 | Examiner Name | Ghali, Isis A. D. |
| | | | | Attorney Docket Number | DURE-007CON2 |

| U.S. PATENT DOCUMENTS | | | | | | |
|--------------------------------|-----------------------|--|--|-----------------------------|---|---|
| Examiner Initials ¹ | Cite No. ¹ | Document Number | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | | |
| IG | | US- 3,998,834 | | 12-21-1976 | Janssen Pharmaceutica N.V. | |
| IG | | US- 5,202,128 | | 04-13-1993 | F.H. Faulding & Co. LTD | |
| IG | | US- 5,378,474 | | 01-03-1995 | F.H. Faulding & Co. LTD | |
| IG | | US- 5,910,301 | | 06/08/1999 | Farr, et al. | |
| IG | | US- 6,703,483 | | 03-2004 | Schiller, Peter | |
| IG | | US- 6,113,937 | | 09-05-2000 | Janssen Pharmaceutica N.V. | |
| | | US- | | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------------|-----------------------|---|-----------------------------|---|---|----------------|
| Examiner Initials ¹ | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ² -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| IG | | WO 90/077333 | 07/12/1990 | Purewal, et al. | | |
| IG | | WO 95/31182 | 11/1995 | Farr, et al. | | |
| IG | | WO 92/02256 | 02/1992 | Yaksh et al. | | |
| IG | | WO 2004/047839 | 06/10/2004 | Chan, et al. | | |
| IG | | EP 0 267 617 A1 | 05/1988 | Patel et al. | | |

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| Examiner Signature | /Isis Ghali/ | Date Considered | 08/24/2006 |
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| | | | First Named Inventor | JOHNSON, RANDOLPH MELLUS | |
| | | | Art Unit | 1615 | |
| | | | Examiner Name | Ghali, Isis A. D. | |
| Sheet | 2 | of | 3 | Attorney Docket Number | DURE-007CON2 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| IG | | Fudin et al. "Use of Continuous Ambulatory Infusions of Concentrated Subcutaneous (SQ) hydromorphone versus intravenous (IV) Morphine: Cost Implications for Palliative Care" Am J Hospice Palliative Care 17:347-353 (2000). | |
| IG | | Physician's Desk Reference, Thomson Healthcare, Montvale, NJ, Ativan (2001) pp. 821. | |
| IG | | Physician's Desk Reference, Thomson Healthcare, Montvale, NJ, Fentanyl (2001) pp. 826. | |
| IG | | Physician's Desk Reference, Thomson Healthcare, Montvale, NJ, Meperidine (2001) pp. 828. | |
| IG | | Physician's Desk Reference, Thomson Healthcare, Montvale, NJ, Morphine (2001) pp. 830. | |
| IG | | Physician's Desk Reference, Thomson Healthcare, Montvale, NJ, Sulfentanil Citrate (2001) pp. 831-32. | |
| IG | | Physician's Desk Reference, Thomson Healthcare, Montvale, NJ, Hydroxyzine Hydrochloride (2001) pp. 1193. | |
| IG | | Physician's Desk Reference, Thomson Healthcare, Montvale, NJ, Duramorph (2001) pp. 1195-1197. | |
| IG | | Physician's Desk Reference, Thomson Healthcare, Montvale, NJ, Duragesic (2001) pp. 1573-1577. | |

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| IG | | Physician's Desk Reference, Thomson Healthcare, Montvale, NJ, Dilaudid (2001) pp. 1619-1623. | |
| IG | | Ramsay, et al. "Immobilization of black bears (Ursus americanus) with orally administered carfentanil citrate", Database Biosis Online!, Biosciences Information Service, Philadelphia, PA US, database accession number PREV 100598404995, abstract (1995); | |
| IG | | Ramsay, et al., "Immobilization of black bears (Ursus americanus) with orally administered carfentanil citrate", Journal of Wildlife Diseases, (1995), 31(3): 391-393 | |
| IG | | Scholz et al. "Clinical Pharmacokinetics of Alfentanil, Fentanyl and Sufentanil" Clin. Pharmacokinet. 31:275-92 (1996). | |
| IG | | Stephens "Intrathecal Narcotics for Labor Analgesia" Am. Fam. Physician 56:463-70 (1997). | |
| IG | | Vercauteren et al. "Postoperative Intrathecal Patient-Controlled Analgesia With Bupivacaine, Sufentanil or a mixture of Both" Anaesthesia 53:1022-7 (1998). | |
| IG | | White "Clinical Uses of Intravenous Anesthetic and Analgesic Infusions" Anesth. Analg. 68:161-171 (1989). | |
| IG | | Willens et al. "Pharmacodynamics, Pharmacokinetics, and Clinical Uses of Fentanyl, Sufentanil, and Alfentanil Heart Lung 22:239-52 (1993). | |
| IG | | Roy and Flynn. "Solubility and Related Physicochemical Properties of Narcotic Analgesics", Pharm Research, 1988, vol. 5, no. 9, pgs 580-586. | |
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